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Patent Docket P1989R1

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of Charles P. Semba Serial No.: 10/697,142 Filed: 30 October 2003 For: PLASMINOGEN ACTIVATOR VARIANT FORMULATIONS	Group Art Unit: 3763 Examiner: Unassigned Confirmation No: 9767 CUSTOMER NO: 09157
	<p>CERTIFICATE OF MAILING</p> <p>I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on</p> <p>September 22, 2006</p> <p><i>Pamela Gavette</i></p> <p>Pamela Gavette</p>

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Applicants submit herewith patents, publications or other information (attached hereto and listed on the attached revised Form PTO-1449) of which they are aware, which they believe may be material to the examination of this application and in respect of which there may be a duty to disclose in accordance with 37 CFR §1.56.

This Information Disclosure Statement is filed in accordance with the provisions of:

- ☒ **37 CFR §1.97(b)**
- within three months of the filing date of the application other than a continued prosecution application under 37 CFR §1.53(d); **or**
 - within three months of the date of entry of the national stage of a PCT application as set forth in 37 CFR §1.491, **or**
 - before the mailing of the first Office action on the merits; **or**
 - before the mailing of the first Office action after the filing of a request for a continued examination under 37 CFR §1.114.
- ☐ **37 CFR §1.97(c)**
- by the applicant after the period specified in 37 CFR §1.97(b), but prior to the

mailing date of any of a final action under 37 CFR §1.113, or a notice of allowance under 37 CFR §1.311, or an action that otherwise closes prosecution in the application, and is accompanied by either the fee set forth in 37 CFR §1.17(p) **or** a statement as specified in 37 CFR §1.97(e), as checked below.

☐ **37 CFR §1.97(d)**

- after the period specified in 37 CFR §1.97(c), and is accompanied by the fee set forth in 37 CFR §1.17(p) **and** a statement as specified in 37 CFR §1.97(e), as checked below.

[If either of boxes 37 CFR §1.97(c) or 37 CFR §1.97(d) is checked above, the following statement under 37 CFR §1.97(e) may need to be completed.]

- ☐ **37 CFR §1.97(e)** Each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this information disclosure statement.
- ☐ **37 CFR §1.704(d)** Each item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application and the communication was not received by any individual designated in §1.56(c) more than thirty days prior to the filing of this information disclosure statement. Therefore, in accordance with the provisions of 37 CFR §1.704(d), the filing of this information disclosure statement will not be considered a failure to engage in reasonable efforts to conclude prosecution under 37 CFR §1.704.
- ☐ The U.S. Patent and Trademark Office is hereby authorized to charge Deposit Account No. 07-0630 in the amount of \$180.00 to cover the cost of this Information Disclosure Statement under 37 CFR §1.17(p). Any deficiency or overpayment should be charged or credited to this deposit account.

A list of the patent(s) and/or publication(s) is set forth on the attached revised Form PTO-1449. Copies of the items listed on the PTO-1449 form are supplied herewith, except for United States patent(s) and United States patent application publication(s) and other documents that are marked with an asterisk (*) in the attached PTO-1449 form. Copies of United States patents and United States patent application publications will not be supplied unless requested by the Office [37 CFR §1.98(a)(2)(iii)]. See Final Rule **1287 OG** (October 12, 2004). Other documents cited with an asterisk have not been supplied because they were previously cited by or submitted to the Office in prior application Serial No. , filed and benefit from the prior application is claimed in this application under 35 U.S.C §120. However, copies of any cited document will be provided in its

entirety at the request of the Office.

☐ BLAST results enclosed:

The undersigned also wishes to bring to the attention of the Examiner BLAST results of computerized alignments of the against sequences contained in the nucleotide and protein databases. The BLAST results are provided in paper form and are identified as reference "BLAST Results A-1 - A-()" (nucleotide) and "BLAST Results B-1 - B-()" (protein) on the PTO Form 1449. Applicant requests that these references also be considered and that the Form 1449 be initialed to indicate the Examiner's consideration of the references.

A concise explanation of relevance of the items listed on PTO-1449 is:

☒ not given

☐ given for each listed item

☐ given for only non-English language listed item(s) [Required]

☐ in the form of an English language copy of a Search Report from a foreign patent office, issued in a counterpart application, which refers to the relevant portions of the references.

In accordance with 37 CFR § 1.97(g), the filing of this information disclosure statement shall not be construed as a representation that a search has been made.

In accordance with 37 CFR § 1.97(h), the filing of this information disclosure statement shall not be construed to be an admission that the information cited in the statement is, or is considered to be, material to patentability as defined in 37 CFR § 1.56(b).

The Commissioner is hereby authorized to charge any additional fees required under 37 CFR 1.16 and 1.17 for this Information Disclosure Statement, or credit overpayment to Deposit Account No. 07-0630. A duplicate copy of this sheet is enclosed.

Respectfully submitted,

GENENTECH, INC.

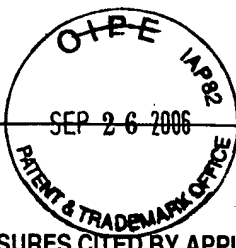
Date: September 22 2006

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FORM PTO-1449

U.S. Dept. of Commerce
Patent and Trademark Office

Atty Docket No.

P1989R1

Serial No.

10/697,142

LIST OF DISCLOSURES CITED BY APPLICANT

(Use several sheets if necessary)

Applicant

Semba Charles P.

Filing Date

30 Oct 2003

Group

Not Assigned

OTHER DISCLOSURES (Including Author, Title, Date, Pertinent Pages, etc.)

70	Abbas, A. E., et al., "Intracoronary Fibrin-Specific Thrombolytic Infusion Facilitates Percutaneous Recanalization of Chronic Total Occlusion" <u>Journal of the American College of Cardiology</u> 46(5):793-798 (2005)
71	Cairolì O.M., "Practical Application: Using Tissue Plasminogen Activator Overnight in Catheter Clearance on Tunnel Catheters Used for Hemodialysis" <u>Proceedings of the 22nd Annual Conference on Dialysis</u> 22(Suppl. 1):S56 (Mar 2002)
72	Daeiagh, P., et al., "Efficacy of Tissue Plasminogen Activator Administration on Patency of Hemodialysis Access Catheters" <u>American Journal of Kidney Diseases</u> 36(1):75-79 (Jul 2000)
73	Dowling, K., et al., "The Use of Tissue Plasminogen Activator Infusion to Re-establish Function of Tunneled Hemodialysis Catheters" <u>Nephrology Nursing Journal</u> 31(2):199-200 (March-April 2004)
74	Eyrich, H., et al., "Alteplase versus urokinase in restoring blood flow in hemodialysis-catheter thrombosis" <u>Am. J. Health-Syst. Pharm.</u> 59:1437-1440 (Aug 1, 2002)
75	Gibson, S. P., et al., "Five Years Experience with the Quinton Permcath for Vascular Access" <u>Nephrology Dialysis Transplantation</u> 6:269-274 (1991)
76	Habowski, S.R. et al., "Use of Tissue Plasminogen Activator (t-PA) for Hemodialysis Catheter Malfunction" <u>J. Am. Soc. Nephrol.</u> 11:185A (2000)
77	Hammes, M. S., et al., "Intraluminal Alteplase (t-PA) Is an Effective Means To Treat Occluded Hemodialysis (HD) Catheters" <u>J. Am. Soc. Nephrol.</u> 12:290A (2001)
78	Little, M. A., et al., "A Longitudinal Study of the Repeated Use of Alteplase as Therapy for Tunneled Hemodialysis Catheter Dysfunction" <u>American Journal of Kidney Diseases</u> 39(1):86-91 (Jan 2002)
79	Moss, A. H., et al., "Use of a Silicone Catheter With a Dacron Cuff for Dialysis Short-Term Vascular Access" <u>American Journal of Kidney Diseases</u> XII(6):492-498 (Dec 1988)
80	National Kidney Foundation, "K/DOQI Clinical Practice Guidelines for Vascular Access, 2000" <u>Am J Kidney Dis</u> 37:S137-S181 (Suppl 1 2001)
81	O'Mara, N.B., et al., "tPA for Central Vein Dialysis Catheter Patency" <u>J. Am. Soc. Nephrol.</u> 11:292A
82	Refino, C. J., et al., "A Variant of Tissue Plasminogen Activator (T103N, N117Q, KHRR 296-299 AAAA) With a Decreased Plasma Clearance Rate is Substantially More Potent Than Activase rt-PA in a Rabbit Thrombolysis Model" <u>Thrombosis and Haemostasis, Abstracts</u> edition 69(6):841 (1993)
83	Roberts, Nicole E. et al., "Outpatient Use of Alteplase (t-PA) in De-Clotting Dialysis Catheters" <u>J. Am. Soc. Nephrol</u> 11:195A (2000)
84	Spry, L. A., et al., "Low-Dose tPA for Hemodialysis Catheter Clearance" <u>Dialysis & Transplantation</u> 30(1):10-13 (Jan 2001)
85	Suhocki, P. V., et al., "Silastic Cuffed Catheters for Hemodialysis Vascular Access: Thrombolytic and Mechanical Correction of Malfunction" <u>American Journal of Kidney Diseases</u> 28(3):379-386 (Sep 1996)
86	U.S. Renal Data System, <u>USRDS 2005 Annual Data Report: Atlas of End-Stage Renal Disease in the United States</u> (National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases), Bethesda, MD (2005)
87	Zacharias, J.M., et al., "Alteplase Versus Urokinase for Occluded Hemodialysis Catheters" <u>The Annals of Pharmacotherapy</u> 37:27-33 (Jan 2003)

Examiner

Date Considered

*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.